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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,763	02/21/2002	Jonathan A. Eppstein	19141.0016U2	4362

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,763	Applicant(s) EPPSTEIN ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,32,38,39 and 49-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 and 57-60 is/are allowed.
- 6) ☒ Claim(s) 1-10,32,38,39,49,50,52-56 and 61-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because several of the pages are headed with inaccurate page numbers. Pages 1-7 are numbered 1/15-7/15, respectively. Page 8 is numbered 8/13. Pages 9-15 are numbered 9/15-15/15, respectively. Pages 25-31 are numbered 10/33-16/33, respectively. Pages 33-48 are numbered 18/33-33/33, respectively. Pages 16-24, 32, 49 and 50 are not numbered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 7 does not illustrate a "cathode 344" as mentioned at page 35, line 12.. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:
- a. On page 8, line 19-27, disclose a method for providing a tatoo which is not mentioned at any other point in the specification.
 - b. On page 68, line 18, "cotrimercially" apparently should read --commercially--.

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- c. On page 75, line 16, "perfon-nance" apparently should read --performance--.
- d. On page 77, line 27, "perforinance" apparently should read --performance--.
- e. On page 78, line 10, "feast" apparently should read --first--.

Appropriate correction is required.

- 4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

- 5. Claim 63 is objected to because of the following informalities: in line 3, --for-- apparently should be inserted before "forming" and in line 8, "or" apparently should read --of--.
- Appropriate correction is required.

- 6. Claim 64 is objected to because of the following informalities: in line 3, --for-- apparently should be inserted before "forming". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5-10, 32, 49, 52-54 and 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 recite the limitation "the movement of the fluid" in line 3. There is insufficient antecedent basis for this limitation in the claims. There is no movement of the fluid recited in the claims prior to these recitations. It is unclear whether the movement recited in the claims refers to the general movement that is inherently characteristic of a fluid or if the movement recited is intended to refer to a particular, purposeful movement of the fluid.

Claims 5 and 6 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the "analyte sensor" relates to the other elements of the invention. For example, the analyte sensor could be its own layer, part of the receiving layer or the substrate layer, the processing circuit of the substrate layer, or a separate element that communicates with the other layers of the multi-layer integrated device.

Claim 7 recites the limitation "said mechanism" in line 5. There is insufficient antecedent basis for this limitation in the claim. There is no mechanism recited in the claim prior to this recitation.

Claim 7 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the "detector" relates to the pad and the strap or

adhesive tape of the invention. For example, the detector could be a part of the pad or a separate element that communicates with the pad.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the “lower section”, “the opening”, “the pad” and “the detector” are related to each other. The claim provides a list of the elements forming the structure; however, the claim fails to disclose how the elements are structurally related to one another.

Claim 52 recites the limitation “the movement of the fluid” in line 5. There is insufficient antecedent basis for this limitation in the claim. There is no movement of the fluid recited in the claims prior to these recitations. It is unclear whether the movement recited in the claims refers to the general movement that is inherently characteristic of a fluid or if the movement recited is intended to refer to a particular, purposeful movement of the fluid.

Claim 52 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the “analyte sensor” relates to the other elements of the invention. For example, the analyte sensor could be its own layer, part of the receiving layer or the substrate layer, the processing circuit of the substrate layer, or a separate element that communicates with the other layers of the multi-layer integrated device.

Claims 61 and 62 recite the limitation "the process" in line 9. There is insufficient antecedent basis for this limitation in the claims. There is no process recited in the claims prior to these recitations.

Claims 63 and 64 recite the limitation "the tissue" in line 3. There is insufficient antecedent basis for this limitation in the claims. There is no tissue recited in the claims prior to these recitations.

Further regarding claim 63, the claim language in "c." renders the claim indefinite as it is unclear whether or not the mechanical element is part of the integrated device.

Claim 64 is further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the "sealing means" is structurally related to the first layer and the sensor of the invention.

Claim 32 recites the limitation "The combination" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no combination recited in the claims prior to this recitation.

Further regarding claim 32, the phrase "and/or probe" renders the claim indefinite as there is no probe recited in the claims prior to this recitation.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2, 3, 5, 6, 9, 38, 39, 49, 50, 52, 53, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. ('403). Garcia et al. teach a glucose medical monitoring system. The system detects the presence or determines the amount of an analyte (glucose) in a biological fluid (blood). An embodiment of the system includes a multi-layer integrated device **602** comprising a receiving layer or pad **648** for receiving a sample of fluid and facilitating movement of the fluid; an analyte sensor **652** for detecting the presence or amount of the analyte in the fluid; a substrate layer **632** that is capable of being in contact with a processing circuit; and a bottom layer **634**. The receiving layer is located underneath at least a portion of the substrate layer and facilitates movement of the fluid to the sensor. The substrate layer can have at least one opening therein to allow an LED source **612** and photodiode sensor **614** access to the analyte sensor. The analyte sensor **652**, LED source **612** and photodiode sensor **614** form a detector that is capable of being in contact with a display. The bottom layer also has at least one opening therein to allow receiving layer or pad access to the fluid. A lancing unit **640** is provided to porate or form an opening in a skin surface. The receiving layer induces the flow of fluid from the opening and to the sensor by wicking although the wicking action may be replaced or assisted by vacuum, capillary action, or other flow or transport processes (col. 13, lines 26-31).

In operation, the first receiving layer or pad is positioned to contact tissue; the tissue is porated to form at least one hole therein; biological fluid is extracted from the opening and collected in the first layer; and the sensor is wetted by the fluid in order to measure a characteristic of the biological fluid. The extraction and movement of the fluid may be induced

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by negative pressures such as vacuum or capillary action or positive pressures such as the pressure that is inherently placed on the device when the lancing device is activated. An opening may be formed in the first layer as the opening is formed in the tissue (col. 15, lines 39-43).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 4 and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. ('403) in view of Erickson et al. ('184). Garcia et al., as discussed hereinabove, teach all of the limitations of the claims except that the integrated fluid harvesting and analysis device is used with interstitial fluid. Erickson et al. teach that is known in the art that blood and interstitial fluid are interchangeable as biological fluids that can be analyzed to provide an indicator of analytes such as glucose within the body. Erickson et al. further teach that both blood and interstitial fluids can be collected using similar lancing and collection devices (col. 5, lines 34-41). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that integrated devices similar to those taught by Garcia et al. could be used to collect interstitial fluids in view of the teachings of Erickson et al. as an alternative means to determine glucose levels within the body of a subject.

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13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. ('403) in view of Mombrinie ('278). Garcia et al., as discussed hereinabove, teach all of the limitations of the claims except that the pad contains a surfactant to facilitate transport of the sample across the pad. Mombrinie teaches that is known in the art that surfactants may be added to wicking materials in order to enhance the wicking capability of the material (col. 4, line 67 - col. 5, line 3). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a pad similar to that taught by Garcia et al. with a surfactant in view of the teachings of Mombrinie in order to enhance the wicking capability of the material, thereby facilitating the transport of fluid across the pad.

Allowable Subject Matter

14. Claims 51 and 57-60 are allowable over the prior art of record.

15. Claims 7, 8, 32, 63 and 64 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

16. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 7, 8 and 51, no prior art of record teach or fairly suggest a method and integrated device for harvesting interstitial fluid where the device includes a pad, held to the body by a strap or adhesive tape, that communicates with a detector to determine the amount of analyte within a fluid sample.

Regarding claims 57-60, no prior art of record teach or fairly suggest an apparatus for

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obtaining a biological fluid sample, where the apparatus includes a device for forming an opening in the skin and a mechanical device that introduces a positive pressure to the skin in order to assist in the fluid flow from the opening.


Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terminiello et al. ('979) teach a test strip and fixture for use with a lancing device. Waner et al. ('252) teach a laser perforator.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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August 19, 2003